



**UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

08/726,093 10/04/96 FUCHS

HM31/0428

TESTA HURWITZ AND THIBEAULT
PATENT ADMINISTRATOR
HIGH STREET TOWER
125 HIGH STREET
BOSTON MA 02110

M SYP-116(7783	
EXAMINER	
ART UNIT MARSCHELLA	PAPER NUMBER

DATE MAILED
18-98

04/28/98

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary

Application No.

08/726,093

Applicant(s)

Fuchs et al.

Examiner

Marschel, Ardin

Group Art Unit

1634



☒ Responsive to communication(s) filed on Jan 26, 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 32-67 is/are pending in the application.

~~☐ Claim(s) 1-31 have been canceled.~~ ~~☐ Claim(s) 1-31 are withdrawn from consideration.~~

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 32-67 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1634.

Applicants' arguments, filed 1/26/98, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 38 and 46-67 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is reiterated and maintained from the previous office action, mailed 8/22/97. Applicants argue that the recitation of colored and resin particles inherently support generic particles and that the detectable moieties of the instant disclosure are not limited to recited embodiments. These arguments are non-persuasive in overcoming the rejection because "written" basis for claim limitations must be present as filed to support amendments. The particle citations are either limited to being colored or resin type particles and not generic as previously noted in the previous office action, mailed 8/22/97, without any further written basis for the noted NEW MATTER limitations. The suggestion regarding detectable moieties

included but not limited to recited embodiments lacks written basis as filed for generic particles and is therefore non-persuasive in overcoming the rejection. This rejection applies to claims 38, 54, and 66.

Claims 46 and 58 have been amended to include the phrase "upstream of a separation zone" without pointing to written basis as filed for this limitation. Consideration of the instant disclosure as filed also has failed to reveal written basis for this phrase. This rejection is necessitated by amendment and also applied to claims dependent from claims 46 and 58.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32, 33, 35-37, 39, 40, 42-47, 50-53, 55, and 56 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Rose.

This rejection is reiterated and maintained from the previous office action, mailed 8/22/97. Applicants argue that PNA strand displacement of homoduplex is the mechanism of formation of PNA/oligonucleotide complexes rather than denaturation via any reagent. This is non-persuasive because an inherent step before PNA hybridization is denaturation of homoduplex. The equilibrium argued by applicants wherein a PNA

molecule replaces an ODN (oligonucleotide) is incomplete in describing the detailed mechanism of such displacement. The detailed mechanism firstly produces two ODN strands via denaturation followed by PNA hybridization to one of the ODNs. It is further noted that applicants have not set forth any publication or support for their allegation of PNA strand displacement without ODN/ODN denaturation first. Applicants also argue that Figure 7 shows mostly ODN/ODN duplex to indicate that denaturing conditions are not present. The operative word therein is "mostly" which admits of some denaturation. It is noted that neither the instant claims nor the Rose disclosure requires complete full denaturation of ODN/ODN duplex. In other words partial denaturation which occurs as depicted in Figure 7 meets both the Rose conditions as well as those of the instant claims.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same

person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 46, 49-51, 54-58, 61, 62, 64, 66, and 67 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wilding et al. (P/N 5,498,392), taken in view of Summerton et al. (P/N 5,217,866).

This rejection is reiterated and maintained from the previous office action, mailed 8/22/97, for instant claims which do not require label on the PNA probes. The instant claims requiring labeled PNA probe practice have been removed from this rejection due to persuasive arguments of applicants on this point.

Claims 32-37, 39-53, 55, and 56 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rose taken in view of Chen et al. (Ref. CN).

This rejection is reiterated and maintained from the previous office action, mailed 8/22/97. The arguments regarding Rose have been responded to above as being non-persuasive. Since these arguments are non-persuasive, the arguments of applicants that Chen et al. does not remedy the deficiencies of Rose are moot as there is no need for Chen et al. to remedy a deficiency

that does not exist.

No claim is allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

April 24, 1998

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER